



A Hidden Healthcare Crisis – Adverse Drug Events

The Problem: Leading Causes of Death in the United States



647,457Heart Disease



599,108 Cancer



173,000 Adverse Drug Events

Adverse drug events have contributed to 100,000 deaths per year, not including 73,000 opioid-related deaths

- 1. Centers for Disease Control and Prevention. National Center for Health Statistics. Leading Causes of Death. https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm. Accessed July 29, 2019.
- 2. US Food and Drug Administration. Preventable Adverse Drug Reactions: A Focus on Drug Interactions. https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm110632.htm. Accessed July 29, 2019.
- 3. National Institute on Drug Abuse. Overdose Death Rates. https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates. Accessed July 29, 2019.



Typology: Adverse Drug Events are NOT Medication Errors

Adverse Drug Events
(all blue areas)

Adverse Drug Reactions
(dark blue area only)

Figure 1. Terms Relevant to Drug-Related Harm [2]

Aug 2014, https://health.gov/hcq/pdf s/ade-action-plan-508c.pdf

A **medication error** is defined as "inappropriate use of a drug that may or may not result in harm;" such errors may occur during prescribing, transcribing, dispensing, administering, adherence, or monitoring of a drug.

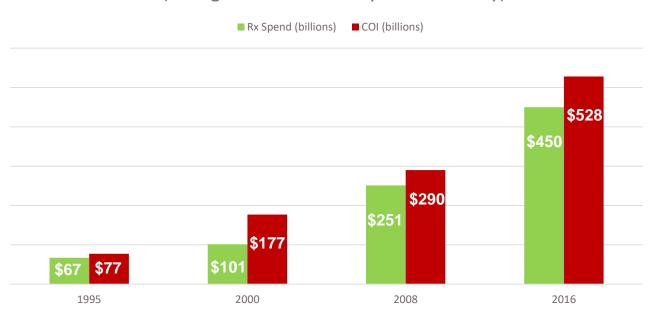
In contrast, ADEs are "harms directly caused by a medication at normal doses."



The Cost of Adverse Drug Events

For every dollar we spend on prescription medication, we spend *more than another dollar* trying to address problems caused by normal medication use.

Rx spending versus cost of illness* 1995-2016 (*Drug-related morbidity and mortality)



- HCUP. Statistical Brief #146, 2013. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb146.pdf
- 2. NCBI. How much will I get charged for this? 2013. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3584078/
- 3. U.S. Department of Health and Human Services. Adverse drug events, 2020. https://health.gov/our-work/health-care-quality/adverse-drug-events
- 4. US Food and Drug Administration. Preventable Adverse Drug Reactions: A Focus on Drug Interactions. https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm110632.htm. Accessed July 29, 2019



Adverse drug events (ADEs) are "harms directly caused by a medication at normal doses."

Medications	2+	4+	7+
ADE risk	13%	38%	82%



1.3 million ER visitsAverage cost per visit \$1,245\$1.62 billion annually²



2 million hospital stays Average cost per stay \$9,700 \$19.4 billion annually¹



More than 3.5 million physician office visits annually in outpatient settings³

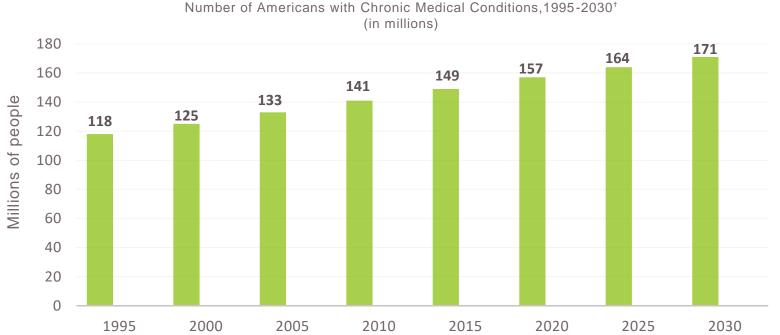


ADEs are the third leading cause of death (2019)

The Rise of Adverse Drug Events

If current trends continue, medication overload will be responsible for at least **4.6 million hospitalizations** between 2020 and 2030 and will cost taxpayers, patients, and families an estimated **\$62 billion**.*

Chronic conditions are on the rise and medications treating them are responsible for a higher prevalence of adverse drug events.



[†] Values for 2005 to 2030 are projections.

^{2000 2005 2010 2015 2020 2025 2030 1.} NCBI. How much will I get charged for this? 2013. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3584078/ Shebab et al. U.S. emergency department visits for outpatient adverse drug events., 2013-2014. NIH.gov. https://dx.doi.org/10.1001%2Fjama.2016.16201



59% of ER Visits from

ADEs are associated with:

Anticoagulants

Diabetes Agents

Opioid Analgesics

Hidden Dangers and Financial Risk

Traditional payer clinical programs have inadequate outcomes.

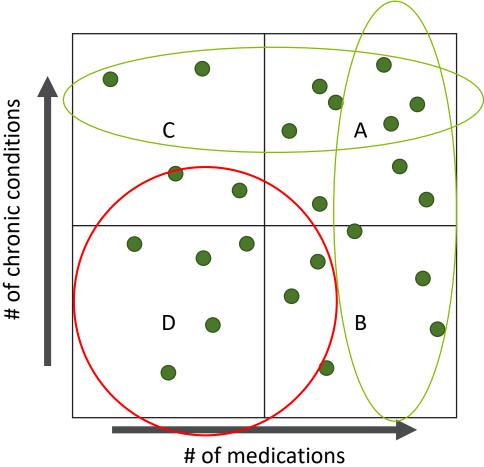
The challenge:

Pharmacy clinical programs have placed emphasis on number of medications, number of chronic illnesses, and high pharmacy spend

- Number of medications is not necessarily associated with risk
- An emphasis on adherence can increase risk if not looked at holistically
- Disease management programs can be siloed, resulting in missed opportunities to intervene and address risks
- Prescription data analysis for traditional programs is retrospective

Missed opportunities for intervention

Are these your emerging high claimants?





Redefining Medication Safety

Traditional One-to-One Drug Analysis





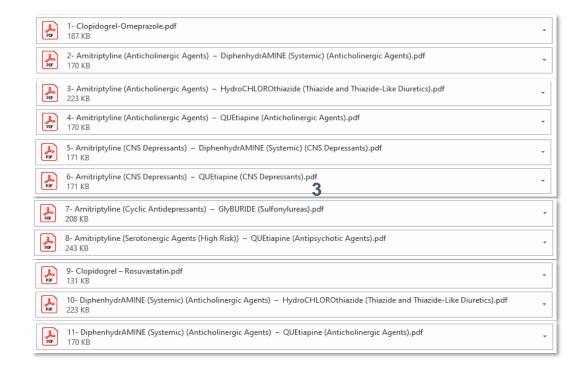


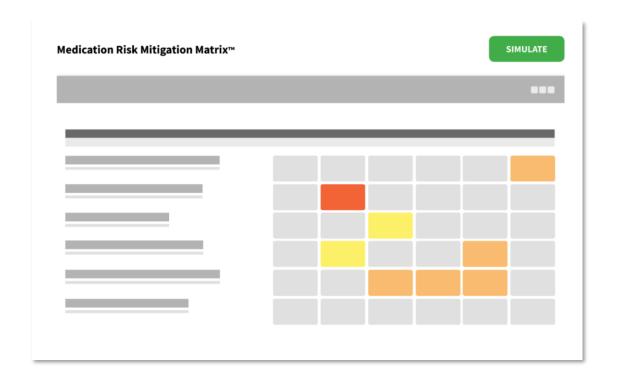
This one-to-one drug interaction software is more than four decades old, and is embedded in EHRs, pharmacies, PBMs, etc.

This software assesses the combined risk of a patient's medications in aggregate and guides pharmacists and prescribers toward individualized medication decision support



Taking complex medication regimen and make them easy to resolve





Lexi-alert system for the same patient: 21 pdf generated

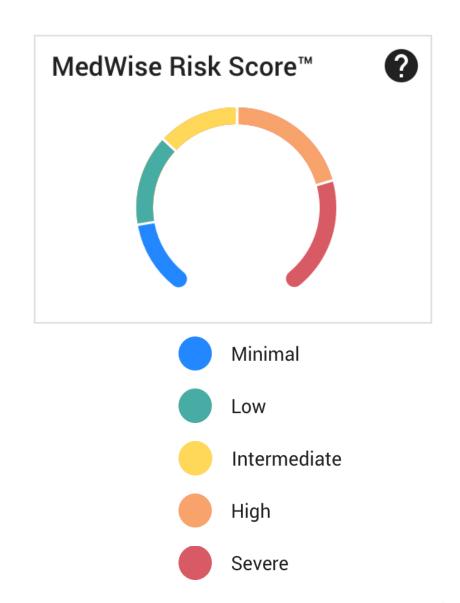


MedWise™ Medication Risk Mitigation Matrix™



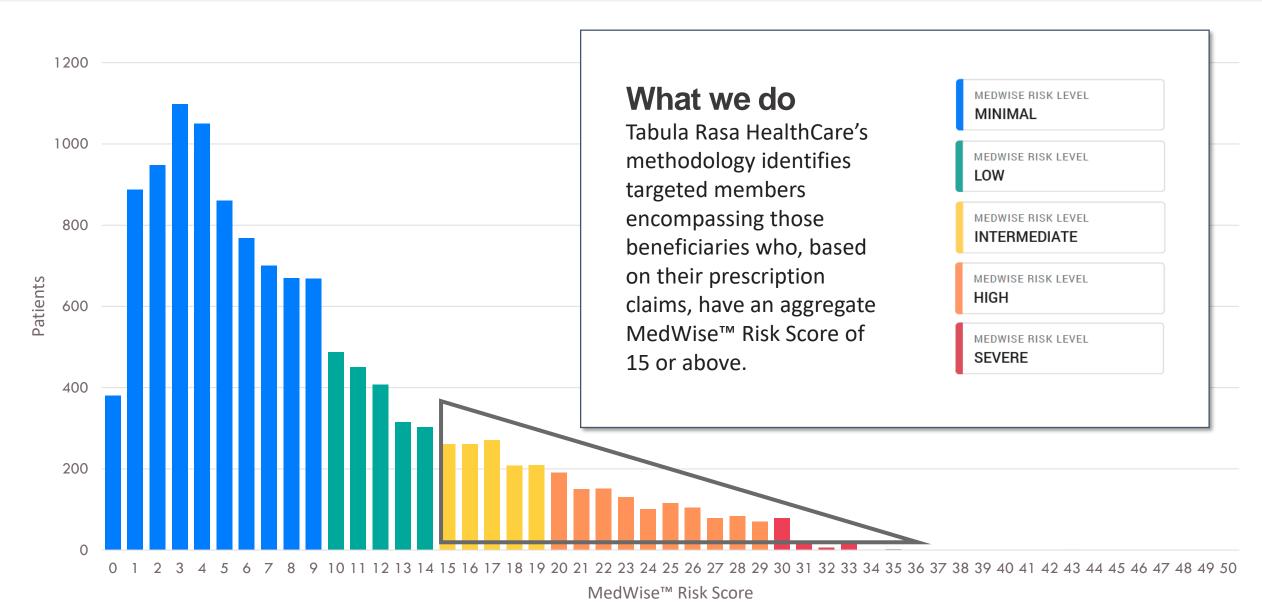
MedWise Risk Score: A New Paradigm

- The MedWise Risk Score™ (MRS) represents a new paradigm in member targeting.
- Traditional member targeting is based on a combination of chronic disease, number of medications, and cost of medications.
- By contract, the MRS targets members that have alterable, pharmacological risk factors identified within their drug regimen for Adverse Drug Events (ADEs).
- The pharmacokinetic (PK) and pharmacodynamic (PD) characteristics of identified active ingredients feed algorithms that compute the MRS.



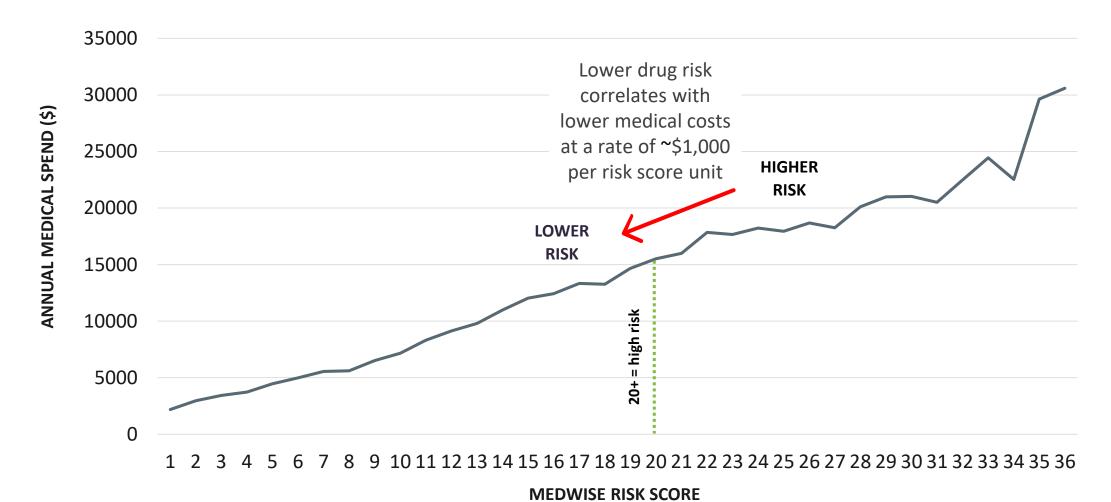


Stratify: Risk Stratify Population





An individual risk score of 15 has a 50% increase in medical spend. With a score of 20, the increase is 100%.





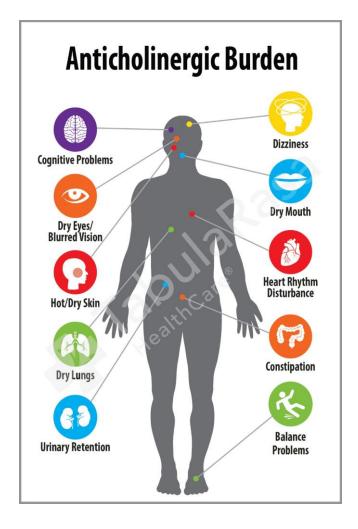


MedWiseTM Proprietary Technology

Improve Patient Outcomes

The MedWise Risk Score™ is supported by the identification of risk factors and side effects

- Adverse Event data derived from the FDA Adverse Event Reporting System (FAERS)
- Side effects of medications with anticholinergic and sedative properties are more pronounced with higher accumulative anticholinergic and sedative burden, respectfully
- Long QT syndrome may lead to ventricular arrhythmias, such as Torsade de Pointes, that can lead to sudden death
- Substrates with greater affinities may cause competitive inhibition





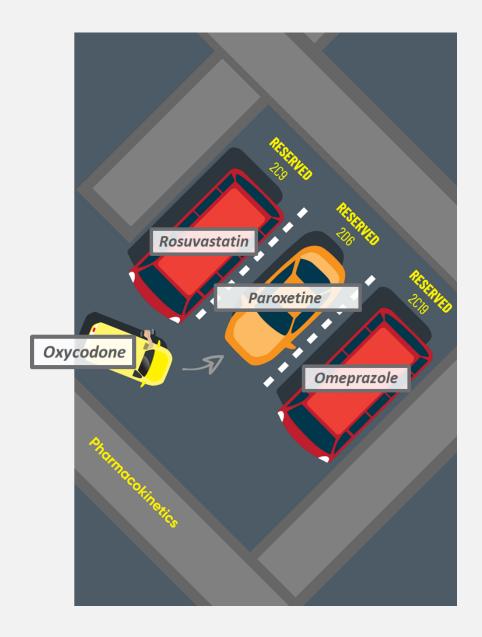
Competitive Inhibition

Approximately 80% of medications are metabolized via the CYP450 system.

 The mechanism can be understood, and simultaneous, multi-drug interactions can be predicted

Substrates of the CYP450 system show various degrees of affinity for CYP450 enzymes.

- Substrates with greater affinities may cause competitive inhibition of the metabolism of other substrates with lower affinities (same enzyme)
 - Active drugs can result in toxicity
 - Inactive drugs (pro-drugs) can result in ineffectiveness





Risks with Opioids

- 1999 to 2016, prescription opioids dispensed nearly quadrupled
 - 630,000+ drug overdose deaths during this time
- Non-fatal overdoses → increased rates of ED observations and hospitalization
- 80% of opioid-related overdose deaths are accidental or unintentional
 - This is due, in part, to drug interactions



SAMHSA. Available at: https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf Rudd RA. *MMWR Morb Mortal Wkly Rep.* 2016;64:1378-82. www.cdc.gov





Outcomes

Enhanced Medication Therapy Management (EMTM)

On September 28, 2015, CMS announced its first Part D Innovation Center model, EMTM to decrease healthcare costs and drive therapeutic outcomes...

5-year program (2017-2022)

5 Part D regions

- Region 7 (Virginia)
- Region 11 (Florida)
- Region 21 (Louisiana)
- Region 28 (Arizona)
- Region 25 (IA, MN, MT, NE, ND, SD, WY) we have over 400 pharmacies provided medications safety reviews

6 Participating Sponsors

- Blue Cross and Blue Shield of Florida, Inc.
- Blue Cross and Blue Shield Northern Plains Alliance
- CVS Health
- Humana Insurance Company
- UnitedHealthcare
- WellCare Prescription Insurance Co.

Flexible and Innovative

Removes regulatory requirements of traditional MTM

Outcomes Focused

Provides standalone Part D plans with Part A and B claims data

Aligned Incentives

Program success is based on achieving 2% reduction in Part A and B



TRHC's EMTM Program



≈200,000

Members in stand-alone Prescription Drug Plans



15% (35,000)

High MedWise Risk Score™



15,130

Engaged in Year 1

19,756

Engaged in Year 2 (>400 pharmacists trained)

24,089

Engaged in Year 3

Enhanced MTM Outcomes



≈ **304,000**

Unique Members in stand-alone PDP over 3 years



20% (43,000)

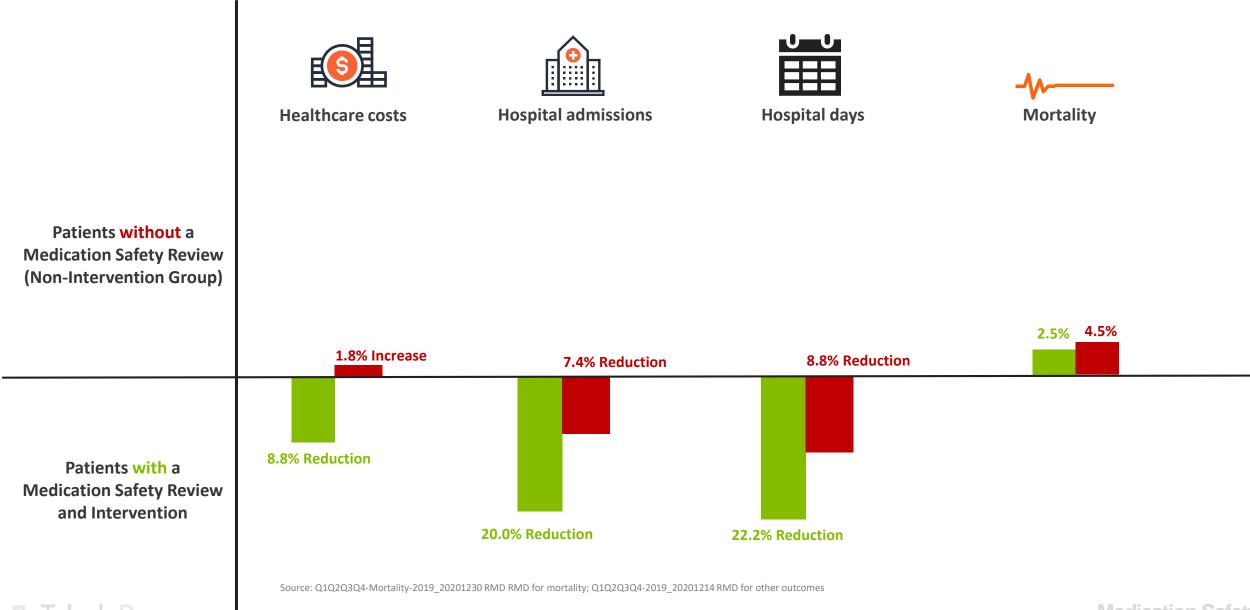
MedWise Risk Stratification identified those at high risk for medication-related problems



\$129 million

Net savings, due most significantly to reductions in ER visits and hospitalizations

The Value of a Medication Safety Review™



The MedWise Risk Score is Predictive of...

Outcome	Risk Score of 10	Risk Score of 20	Risk Score of 30
Outpatient Visits (Average # Per 100 Members in 2019)	717 (706, 728)	1,170 (1,152, 1,188)	1,622 (1,591, 1,654)
Hospital Admissions (Average # Per 100 Members in 2019)	21 (20, 22)	44 (43, 45)	67 (64, 69)
Days in Hospital (Average # Days Per Member in 2019)	1.2	2.6 (2.4, 2.7)	3.9 (3.8, 4.1)
Days in Skilled Nursing Facility (SNF) (Average # Days Per Member in 2019)	2.2 (2.0, 2.3)	4.8 (4.5, 5.0)	7.4 (6.9, 7.8)
ADEs (Parts A and B) (% of Members with ≥1 ADE in 2019)	5.0 (4.8, 5.1)	9.3 (9.1, 9.6)	13.7 (13.3, 14.1)
Falls (Parts A and B) (% of Members with ≥1 Fall in 2019)	8.8 (8.6, 8.9)	15.3 (15.0, 15.6)	21.8 (21.3, 22.3)
Mortality (% of Members Who Died in 2019)	4.4 (4.3, 4.6)	7.8 (7.6, 8.1)	11.2 (10.7, 11.6)
Total Cost (Parts A/B) (Average \$ Per Member in 2019)	\$9,005 (\$8,818, \$9,193)	\$16,574 (\$16,267, \$16,881)	\$24,143 (\$23,616, \$24,670)

Increasing risk score is associated with poorer clinical outcomes and higher costs.

Source: PSM-Mortality-Q3Q4-2018_20201230 RMD for mortality; MRM_Story_Y18Y19_20201123 RMD for other outcomes

Cohort Criteria for Mortality: All members for whom death can be observed in 2019 and who have risk score information available in the second half of 2018. Members who became ineligible for the EMTM program partway through 2019 for a reason other than death are excluded.

Cohort Criteria for Other Outcomes: All members with uninterrupted eligibility for the 2019 EMTM program year

Sample: 184.258 for mortality; 195,541 for other outcomes

Note: For mortality, we examine the relationship between (a) the maximum risk score in the last six months of 2018 and (b) the likelihood of dying in 2019. For the remaining outcomes, we examine the relationship between (a) the maximum risk score in 2018 and (b) the corresponding outcome in 2018.

ESRD members are excluded.

Emergency Department (ED) visits have been removed due to a pending definition change.





Kentucky Medicaid Medication Risk Reduction Program

NJ Senate Bill No. 887 - Timeline

Senate Bill No. 887

<u>Sweeney, Stephen M.</u> as Primary Sponsor <u>Greenstein, Linda R.</u> as Primary Sponsor <u>Gopal, Vin</u> as Co-Sponsor

01/27/2020 Introduced in the Senate, Referred to Senate Health,

Human Services and Senior Citizens Committee

09/14/2020 Reported from Senate Committee as a Substitute, 2nd

Reading

09/14/2020 Referred to Senate Budget and Appropriations

01/21/2021 Reported from Senate Committee with Amendments,

2nd Reading

01/28/2021 Passed by the Senate (32-0)

01/28/2021 Received in the Assembly, Referred to Assembly

Human Services Committee

03/17/2021 Reported and Referred to Assembly Appropriations

Committee

Committee Voting:

SHH 9/14/2020 - r/SCS - Yes {5} No {1} Not Voting {2} Abstains {0} SBA 1/21/2021 - r/Sca - Yes {12} No {0} Not Voting {0} Abstains {0}

Assembly Bill No. 4790

<u>Downey, Joann</u> as Primary Sponsor <u>Benson, Daniel R.</u> as Primary Sponsor

10/08/2020 Introduced, Referred to Assembly Human Services

Committee

03/17/2021 Reported as an Assembly Committee Substitute and

Referred to Assembly Appropriations Committee

Committee Voting:

AHU 3/17/2021 - r/ACS - Yes {7} No {0} Not Voting {0} Abstains {0}





The State of New Jersey Budget in Brief – Fiscal Year 2022 Link

"The Administration is also supportive of current legislation that will apply a risk reduction model to prescription drug services under the Medicaid program." – February 2021



NJ Senate Proposes TRHC's Enhanced MTM Model for Medicaid...

3. The Division of Medical Assistance and Health Services in the Department of Human Services shall contract with a third party entity to apply a risk reduction model to prescription drug services provided under the Medicaid program established pursuant to P.L.1968, c.413 (C.30:4D-1 et seq.), for the purpose of identifying and reducing simultaneous, multi-drug medication-related risk and adverse drug events, enhancing compliance and quality of care, and improving health-related outcomes while reducing total cost of care in a measurable and reportable manner. In carrying out this purpose, the model, at a minimum, shall leverage Medicaid prescription drug claims data, pharmacokinetic and pharmacodynamic sciences, appropriate technologies, clinical call centers located in New Jersey and staffed by board-certified pharmacists licensed pursuant to P.L.2003, c.280 (C.45:14-40 et seq.), and include coordination of services with a network of local community pharmacies located throughout the State. For the duration of the contract, the division shall share the medical and pharmacy claims data for all Medicaid beneficiaries with the third party administering the model for the purposes of effectuating the model, which claims data shall include historical data.

NJ Senate Press Release (Sept 15, 2020)....

Yesterday, the Senate Health, Human Services and Senior Citizens Committee approved the Sweeney-Greenstein bill, which, among other things, requires the Department of Human Services to contract with a third party to apply a risk reduction model to prescription drug services under the Medicaid program.

Tabula Rasa HealthCare, Inc., a healthcare technology company, estimates that New Jersey will generate annual cost savings in excess of \$80 million if such a model is applied to the Medicaid program.

Nationwide, adverse drug events cause health problems that contribute to more than 3.5 million physician office visits, 1.3 million emergency room visits and 350,000 hospitalizations, cause extended lengths of stay and are the leading preventable cause of hospital readmissions, Dr. Calvin Knowlton, Tabula Rasa's CEO, told the Senate Health Committee yesterday.



Testimony Before the Senate Health Committee – September 14

New Jersey Senate Health, Human Services and Senior Citizens Committee

Testimony: Senate Bill No. 887

September 14, 2020 By Calvin H. Knowlton, BSc Pharm, MDiv, PhD CEO, Chairman & Founder, Tabula Rasa HealthCare, Inc. (Moorestown, NJ)

Chairman Vitale, members of th CEO, Chairman & Founder, of I testify today in support of a propen Enhanced Medication Therapy I reduce total cost of care across (Moorestown) New Jersey, that that these programs work and I



The Promise of Enhanced MTM for New Jersey Medicaid

New Jersey's approximate Medicaid population is comprised of 1,496,000 beneficiaries. (CMS, 2019). The Medicaid subpopulations of Aged, Blind and Disabled (ABD) with Medicare and those in Nursing Homes have a higher prevalence of polypharmacy and more closely mirror our extensive experience across Medicare markets. When we apply our Economic, Clinical and Humanistic Outcomes (ECHO) model of Enhanced MTM programs for government sponsored-plans, we estimate that a Medicaid Enhanced MTM program like ours in New Jersey will generate annual cost savings in excess of \$80 million. When we add to these two cohorts to the balance of New Jersey's Medicaid population, the annual cost savings potential is even greater.



NJ Senate Bill No. 887 - Timeline

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Gopal, Vin as Co-Sponsor

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Assembly Bill No. 4790

<u>Downey, Joann</u> as Primary Sponsor <u>Benson, Daniel R.</u> as Primary Sponsor

10/08/2020 Introduced, Referred to Assembly Human Services Committee 3/17/2021 Committee Voted – referred to Appropriations Committee



Savings Initiatives

In addition to the above health benefits reforms, the budget includes approximately \$250 million in departmental savings, and one-time reductions of approximately \$700 million due to the availability of federal resources in FY2022. The Administration was pleased to work with its partners in the Legislature to enact P.L.2021, c.4, which reforms the State procurement process to permit reverse

12

The FY2022 Budget

auctions for the procurement of goods and services outside of contracts for covered health care services. The Administration is also supportive of current legislation that will apply a risk reduction model to prescription drug services under the Medicaid program.

February 23, 2021



NJ Senate Bill No. 887 - Timeline

Senate Bill No. 887

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The State of New Jersey Budget in Brief – Fiscal Year 2022 Link

"The Administration is also supportive of current legislation that will apply a risk reduction model to prescription drug services under the Medicaid program." – February 2021

Signed by Governor Murphy

7/2/2021 Approved P.L.2021, c.151.



Medicaid Medication Risk Reduction Program

▶ We help state Medicaid improve health-related outcomes and reduce total cost of care.

The **Core Components** of this Program Includes:

- The use of pharmacokinetic and pharmacodynamic sciences leveraging MedWise Science
- Innovative technical solutions to facilitate medication risk assessments that identify members who are at high risk for adverse drug events
- A nationwide network of community pharmacies and clinical contact centers staffed with certified pharmacists to deliver
 MedWise Safety Reviews

Value Proposition:

Through our data-driven technology and solutions, TRHC empowers state Medicaid to prevent adverse drug events and optimize medication regimens. TRHC can help reach the following goals:

- Improve member outcomes
- Reduce hospitalizations and emergency room visits
- Lower healthcare costs and manage risk

Our MedWise Science demonstrates real cost savings, providing positive returns on investment. TRHC is disrupting the fields of medication safety in multiple areas of healthcare, including through our participation in the CMS EMTM pilot program. With ample experience facilitating medication safety solutions, TRHC serves a variety of complex populations across the U.S.



MedWise® Risk Reduction Model for State Medicaid

Receive pharmacy claims or medication profiles*



Perform simultaneous multi-drug analysis using MedWise



Identify members at highest risk for an adverse drug event



4 Conduct medication reconciliations



Complete Medication
Safety Reviews™ using
Medication Risk
Mitigation Matrix™



6 Communicate sciencedriven interventions with members



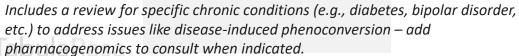
Send action plans to members and physicians



B Document and improve outcomes







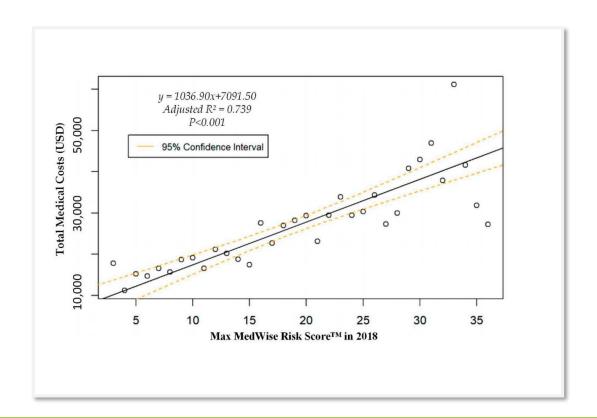


EMTM – Community Pharmacist service fee: \$175/MSR – initial and \$125/MSR for follow-up.



Additional Outcomes

Program of All-Inclusive Care for the Elderly (PACE) Results



Results: as each unit increase in the MRS corresponded to over \$1,037 USD in additional annual medical spending, three additional annual ED visits per 100 participants per year, and two additional hospitalizations per 100 participants per year.



Association of a Novel Medication Risk Score with Adverse Drug Events and Other Pertinent Outcomes Among Participants of the Programs of All-Inclusive Care for the Elderly

David L. Bankes ¹, Hubert Jin ², Stephanie Finnel ², Veronique Michaud ³, Calvin H. Knowlton ⁴, Jacques Turgeon ³ and Alan Stein ²,*

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- Chief Executive Officer, Tabula Rasa HealthCare, Moorestown, NJ 08057, USA; CKnowlton@trhc.com
- * Correspondence: AStein@trhc.com

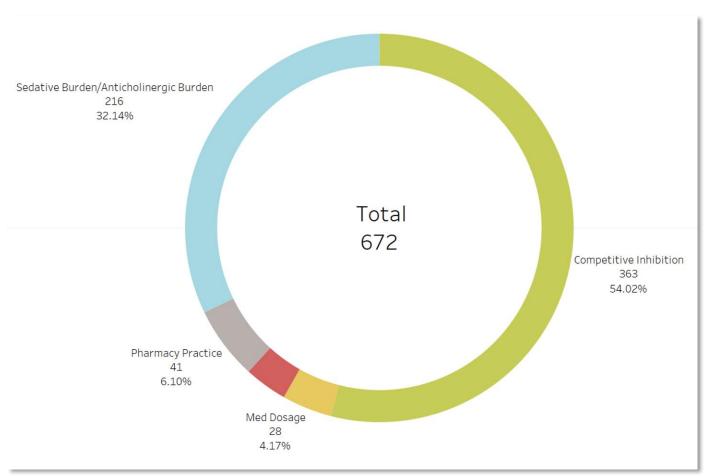
Received: 22 April 2020; Accepted: 15 May 2020; Published: 20 May 2020

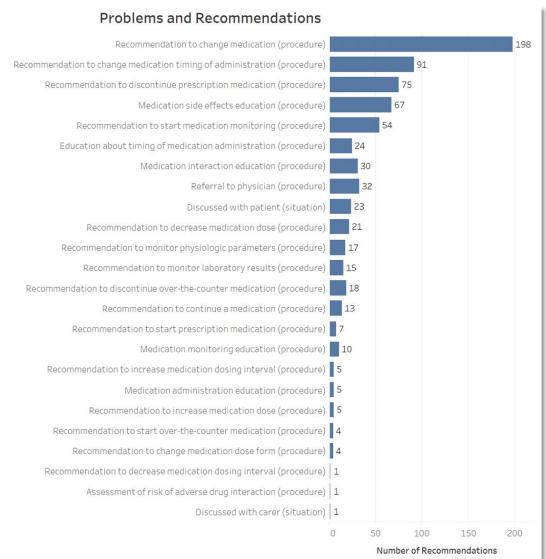


Abstract: Preventable adverse drug events (ADEs) represent a significant public health challenge for the older adult population, since they are associated with higher medical expenditures and more hospitalizations and emergency department (ED) visits. This study examines whether a novel medication risk prediction tool, the MedWise Risk ScoreTM (MRS), is associated with ADEs and other pertinent outcomes in participants of the Programs of All-Inclusive Care for the Elderly (PACE). Unlike other risk predictors, this tool produces actionable information that pharmacists can easily use to reduce ADE risk. This was a retrospective cross-sectional study that analyzed administrative medical claims data of 1965 PACE participants in 2018. To detect ADEs, we identified all claims that had ADE-related International Classification of Diseases and Health Related Problems, 10th revision (ICD-10) codes. Using logistic and linear regression models, we examined the association between the MRS and a variety of outcomes, including the number of PACE participants with an ADE, total medical expenditures, ED visits, hospitalizations, and hospital length of stay. We found significant associations for every outcome. Specifically, every point increase in the MRS corresponded to an 8.6% increase in the odds of having one or more ADEs per year (OR = 1.086, 95% CI: 1.060, 1.113), \$1037 USD in additional annual medical spending (adjusted R^2 of 0.739; p < 0.001), 3.2 additional ED visits per 100 participants per year (adjusted R^2 of 0.568; p < 0.001), and 2.1 additional hospitalizations per 100 participants per year (adjusted R^2 of 0.804; p < 0.001). Therefore, the MRS can risk stratify PACE participants and predict a host of important and relevant outcomes pertaining to medication-related morbidity.



Summary of Interventions

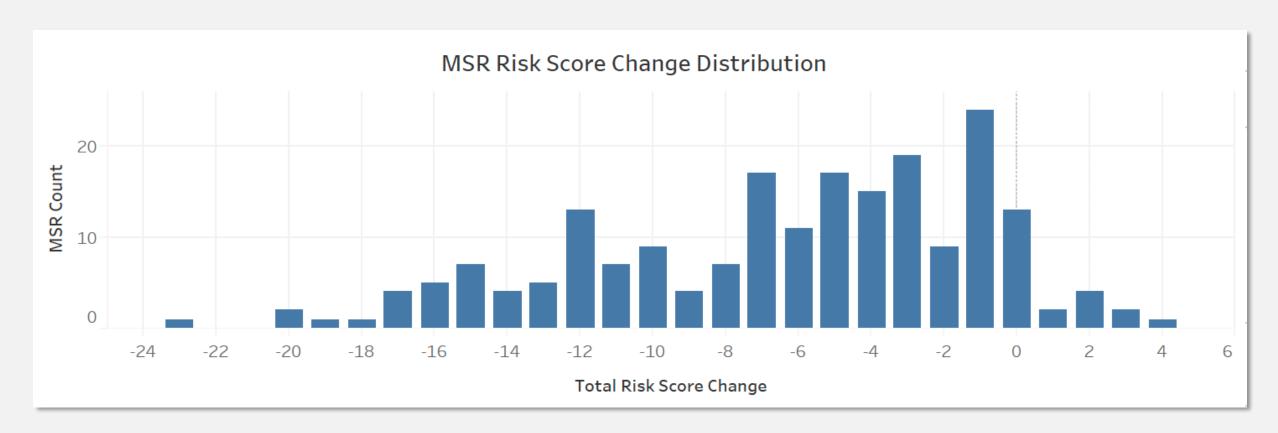






Medication Safety Program Outcomes

Average risk score reduction of 6.35





TRHC's ECHO - PACE, EMTM, Health Plans

A Preview of Outcomes Pharmacists Produce with the New MedWise System

		eview	
Metrics	PACE Prospective/Monthly touches	Retrospective/One touch per year	SaaS Hybrid
PMPY (\$) Documented Savings	\$3,996 PMPY*	\$2,818 PMPY**	\$2,596 PMPY***
Hospitalizations	42.9%	51%	22.5%
ER Visits	20.4%	23%	28.2%
ROI (\$)	13:1	5:1	10:1

^{*} Overall savings based on hospitalization reduction across the entire PACE census.

ECHO = Economic, Clinical, and Humanistic Outcomes

ER = emergency room

PMPY = per member per year

ROI = return on investment

SaaS = software as a service



^{**} One and sometimes two telephonic interventions per year.

^{***} Health Plan's pharmacists were trained in use of MedWiseTM, and collaborated with the plan's physicians and patients.

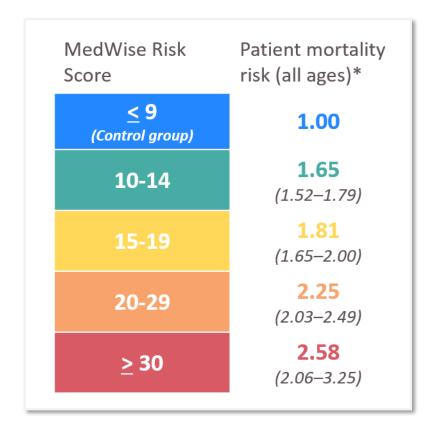
Reducing the MedWise Risk Score™ Can Reduce Premature Death

Recent study: Longitudinal association of a medication risk score with mortality among ambulatory patients acquired through electronic health record data

Authors: Amanda Rondinelli Ratigan, PhD, MPH, Veronique Michaud, PhD, Jacques Turgeon, PhD, Ravil Bikmetov, PhD, Gabriela Gaona Villarreal, MPH, Heather D. Anderson, PhD, Gerald Pulver, PhD, and Wilson D. Pace, MD

- Analyzed 427,000 patient EHRs
- Among patients with high (>20) risk score aged 30 to 49 years, a one-point increase in risk score correlated with an 11% increase in mortality
- Higher risk scores correlate independently with increased mortality

Ratigan AR, Michaud V, Turgeon J, Bikmetov R, Villarreal GG, Anderson HD, Pulver G, Pace WD. Longitudinal association of a medication risk score with mortality among ambulatory patients acquired through electronic health record data. *J Patient Saf.* 24 Mar 2021.

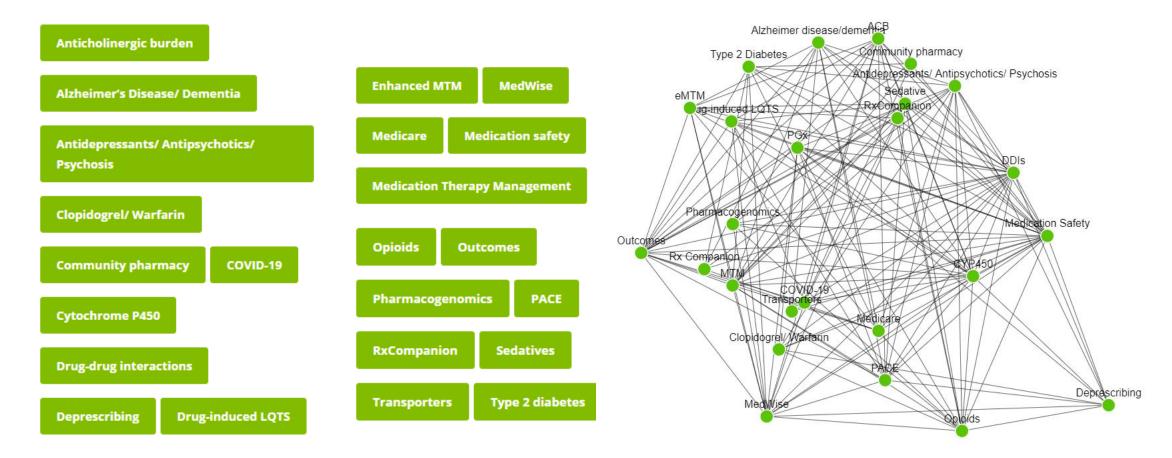


^{*}Hazard ratio represents the likelihood of mortality at a given point in time



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+ Successfully authored at least one publication in a peer-reviewed journal <u>every</u> week of the year (2020) through current





Source: https://www.tabularasahealthcare.com/research-development/publications-and-reports/



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Questions? Next Steps...

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